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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,648	01/29/2004	James A. Hoxie	53893-5046-00	6515

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

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09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,648	HOXIE ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *5,6,8,9,11,14,15 and 17-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,10,12,13 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed June 28, 2007 in response to the Office Action of December 27, 2006 is acknowledged and has been entered. Claims 2, 4, 7, 10, 12, 13, 16 have been amended.

Claims 5, 6, 8, 9, 11, and 14, 15, and 17-72 are withdrawn. Claims 1-4, 7, 10, 12, 13, and 16 are under examination in the present Office action.

Election/Restrictions

Applicant's amendment of claims 7 and 10 to correct the amino acid residue number from 393 to 391 is acknowledged. Thus, because this amendment is a correction, it is not regarded as switching of the invention.

Priority

Applicants submit that all claims referring to SEQ ID NO: 5 should properly be granted priority to the provisional application 60/443,364, because although a separate sequence listing was not submitted with the provisional application, the sequence depicted in SEQ ID NO: 5 was nonetheless disclosed in provisional application 60/443,364. The Office acknowledges that SEQ ID NO: 5 was disclosed in provisional application 60/443,364 and thus the claims reciting SEQ ID NO: 5 are given priority to the provisional application 60/443,364.

Applicants acknowledge that the SEQ ID NO: 11 is not disclosed in provisional application 60/446,364. Thus claims reciting SEQ ID NO: 11 are given priority date of January 29, 2004, the filing date of the present application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of claims 1-5, 7, 10, 12, 13, and 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is maintained**.

With regard to the claimed derivatives, Applicants argue that the specification provides a definition of the claimed derivatives: "derivatives are peptides which may be altered in one or more amino acids such that the peptide (or DNA) is not identical to the sequences recited herein, but has the same property as the peptides disclosed herein, in that the peptide has the property of having a detectable function compared with the wild type polypeptide." In response to Applicant's arguments it is the Office's position that Applicants definition of a term "derivative" is not sufficient to allow the skilled artisan to decipher what are the metes and bounds of the claimed derivatives. Thus because the metes and bound of the claimed derivatives cannot be determined the rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 1-5, 7, 10, 12, 13, and 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicants argue that the specification provides that the term "fragment," as applied to a polypeptide, "may ordinarily be at least about seven contiguous amino acids, typically, at least about fifteen

contiguous amino acids, more typically, at least about thirty contiguous amino acids, typically at least about forty contiguous amino acids, preferably at least about fifty amino acids, even more preferably at least about sixty amino acids and most preferably, the peptide fragment will be greater than about sixty contiguous amino acids in length." Applicants further argue that the specification sets forth multiple specific examples of gp 120 polypeptides according to the present invention and that the fragments of the present invention have been defined by their biological activity that is the ability to bind to a chemokine receptor without the requirement that the peptide also binds to CD4. Applicants also argue that the skilled artisan would understand that the claimed fragment would necessarily share the amino acid sequence homology with SEQ ID NO: 5.

In response to Applicant's arguments it is the Office's position that the Applicants were not in possession of the claimed fragments at the time when the application was filed for the following reasons. The claims broadly recite 120 polypeptide fragments without further providing the critical core structures of the claimed fragments or providing a structure and function correlation. The specification broadly refers to a large number of fragments, without specifying which specific fragment sequences possess the expected functionality. Additionally, describing the claimed fragments, in the specification by their functions, as argued by the Applicants, does not provide written description for the structures of the claimed fragments. Thus in view of the reasons discussed above, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Hasel et al. (US Patent 5,886,163) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicants argue that Hasel does not anticipate the present invention because Hasel dos not disclose every element of the claimed invention. Applicant argue that Hasel's mutations, at the specific position within the C4 domain of the V3 loop comprised within the HIV-1 gp120, have different function than the compensatory mutation of the present invention. Particularly, the purpose of the amino acid substitution of Hasel is that Hasel's point mutations were selected based on their ability to reduce the affinity of the mutant gp120 protein for CD4 by at least two fold. Applicant further argue that, in contrast to Hasel's mutations the compensatory mutation of the present invention is made "for the purpose or with the result of altering the properties and/or activity of the polypeptide in response to a second change affecting the properties and/or activity of the polypeptide (...)".

In response to Applicants arguments, it is the Office's position that Hasel does disclose the present invention including the compensatory mutation as the compensatory mutation is defined in the present specification, because Hasel's mutation does result in altering the property and /or activity of the mutated gp120 polypeptide. Additionally, Applicants arguments with regard to the distinct functions of the Hasel's mutation and the compensatory mutation of the present invention fail to distinguish the structure of the presently claimed mutated HIV-1 gp120 polypeptide, over the structure of Hasel's mutated HIV-1 gp120 polypeptide. It is also noted that the present claims are broadly drawn to mutants, fragments and derivatives of the gp120

polypeptide. Thus because Hasel discloses mutants of gp120 protein, therefore the structures of Hasel's mutants read on broadly claimed mutants, fragments and derivatives of gp120 polypeptide of the present invention. Thus because Hasel anticipates the claimed invention as discussed above and on the record, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday – Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB
Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 9-17-07
Primary Examiner, TC1600